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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,710	12/01/2000	Volker Schreiner	Beiersdorf 688-VMM	7950

7590

12/20/2001

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EXAMINER

BERMAN, ALYSIA

ART UNIT

PAPER NUMBER

1619

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DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,710

Applicant(s)

SCHREINER ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of the preliminary amendment filed December 01, 2001 and the information disclosure statement filed March 12, 2001. Claims 1-4 have been canceled. Claims 5-26 have been added and are pending.

Information Disclosure Statement

2. The information disclosure statement filed March 12, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not provide legible copies of all the documents. It has been placed in the application file, but the information referred to therein and crossed through has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

3. The disclosure is objected to because of the following informalities:

4. Applicants disclose at page 4, bottom of the page that the compound epicatechin corresponds to the structure presented there. However, an STN REGISTRY file search of the term epicatechin resulted in a different structured. Please see attached REGISTRY file printout from the STN database. It is unclear if Applicant intends to

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disclose the compound epicatechin or the compound that corresponds to the structure at the bottom of page 4. Clarification is requested.

5. Example 2 at page 17 discloses that the green tea extract is stirred into the water phase. However, there is no disclosure of green tea extract in Example 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 5-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment and/or care of dry skin conditions, does not reasonably provide enablement for the prophylaxis of dry skin conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. It is virtually impossible to support prophylaxis of a dry skin condition because the presentation of a dry skin condition is unpredictable. Further, it is unpredictable that the dry skin condition would never present after treatment. The only way to provide support for prophylaxis of a dry skin condition would be to show that the condition would necessarily have presented without treatment and that the condition never occurred for the lifetime of the recipient after treatment. The specification does not provide any evidence of prophylaxis of any dry skin conditions. It would take undue experimentation for one skilled in the art to determine prophylaxis of a dry skin condition

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by using the instant invention. Therefore, the specification is not enabled for the prophylaxis of dry skin conditions.

8. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide a written description of strengthening the lipid barrier or increasing the synthesis rate of ceramides of human skin by application of the instant invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

10. Claims 5-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 5-12 are indefinite because claims 5 and 12 recite the phrase "dry skin conditions". The specification does not provide an explanation or definition of what Applicant intends by the phrase "dry skin conditions". The metes and bounds of the claims cannot be determined.

12. Claims 5-11 are indefinite because claim 5 recites "a therapeutically effect amount" in lines 2-3. It is unclear what Applicant intends by this phrase. Correction is requested.

13. Claim 8 is indefinite because it is unclear what compound Applicant intends to claim based on the disclosure at page 4 of the specification as explained above.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 5-20 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by the HCAPLUS abstract of BR 9303217 A (217).

BR '217 is directed to extracting flavanoids from tea leaves for use in cosmetics (title). The flavanoids extracted from the tea leaves include catechin, epicatechin, epigallocatechin and gallocatechin, *inter alia*. The catechins provide various benefits such as skin-softening, skin-moisturizing and emolliency. BR '217 teaches application of the cosmetics containing catechins to the skin for softening and moisturizing the skin, which is equivalent to treating dry skin conditions.

16. Claims 5-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,523,090 (090).

US '090 is directed to skin treatment compositions that contain a xanthine (caffeine), an inositol phosphoric acid and/or alpha hydroxy acid (title). The compositions may contain additional active components such as moisturizers (col. 6, lines 54-61). Examples 10-12 at columns 12-14 contain green tea extract, caffeine and vitamins E and A. Example 12 additionally contains epicatechin and carnitine. The green tea extract is contained in the compositions in an amount of 0.2 wt% of 0.5 wt.%. The epicatechin is in an amount of 0.1 wt.%. The compositions are applied to the skin to

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generally enhance the quality and flexibility of the skin, thereby encompassing treatment and/or care of dry skin conditions (col. 8, lines 48-53). US '090 teaches compositions for application to the skin that contain green tea extract and epicatechin as instantly claimed.

17. Claims 13-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/26705 (705).

WO '705 is directed to composition containing a catechin compound for application to the skin (abstract). The catechins are obtained from green tea leaves (page 2, lines 5-10 and page 3, lines 12-15). For structures that correspond to the instantly claimed structures of claims 7 and 8, see page 2, lines 20 to page 3, line 11. The catechin compound makes up from 0.1-40 wt.% of the composition (page 4, lines 25-28). WO '705 teaches that the catechin compound may be used in purified form or as a mixture as in the green tea extract. For application to the skin see page 5, lines 2-21.

18. With regard to claim 24, the composition claimed does not require any additional limitations because the components of claim 24 are optional. In any event, Applicant admits at page 4, 1st paragraph that tea extracts typically contain caffeine, vitamins, sugars, minerals, amino acids and lipids. Therefore, cosmetics containing the tea extracts of the references would inherently contain these additional components. Burden is shifted to Applicant to show that the tea extracts of the references do not contain these additional components.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 5-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the HCAPLUS abstract of BR 9303217 A (217) in combination with US 5,523,090 (090).

BR '217 teaches all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejections above. It does not teach the weight percent ranges of the catechin of instant claims 21-23. US '090 teaches all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not explicitly teach treatment and/or care of dry skin conditions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the compositions of BR '217 using the amounts of green tea

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extracts and catechins as taught by US '090 with the reasonable expectation of obtaining moisturizing skin care compositions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached during core hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3704 or 703-305-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
December 4, 2001


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